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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/521,907	03/09/2000	Stale Petter Lyngstadaas	49121	2801

21874 7590 09/30/2003

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EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 09/30/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

521,907

Applicant(s)

LYNGSTADAS et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 4/30/03
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 28-35, 41-55, 60 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 28-35, 41-55, 60 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

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Amendment of 4/30/03 (Paper 15) has been entered. Claims 28-35, 41-55 and 60 are pending and under examination.

The amendment has overcome previously stated rejections under 35 U.S.C. 112 and objections under 37 CFR 1.75.

New grounds of rejection under 112 follow.

Claims 29-31, 50, 54 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The dependent claims are confusing in relation to amended base claim 28. Since claim 28 requires application of active enamel substance to the graft, it is not clear, as to at which point in the sequence of steps in claim 28, the enamel substance would also be applied to the graft bed area (claims 29-31), or would be administered in vivo (claim 50) assuming this means the host who will receive the graft), or would be administered to the mammal (claim 54). Alternatively these claims may be considered inconsistent with base claim 28, because they administer the enamel matrix to the graft host, while claim 28 administers the enamel matrix to the graft.

Claim 60 is confusing. Is the "non-mineralized tissue" of claim 60 the "graft" of claim 28?

Claims 28-35, 41-55 and 60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Amended claim 28 recites new matter.

Specifically, the step of “administering to said graft...” at lines 5-6 is not supported. To the contrary, the examiner finds the original disclosure supports, at the broadest “administering to a mammal” (claim 28), which step would be understood as the host/graft recipient, not the graft. Further, claims 29-31 referred to administering the enamel matrix proteins to the “graft bed”, not the graft. Likewise, the examiner finds no teachings at specification pages 1-4, or anywhere else, of anything other than what is taught in the above-mentioned claims. More particularly, there is no specific hint of or recitation of “administering to said graft” (separate from the graft bed) anywhere in the disclosure. Applicant has not adequately addressed previous new matter rejection of claims 61, 63.

Further, while applicant states (Paper 15, page 2) that the amendment of claim 28, is supported at pages 1-4 of the specification, the examiner cannot find a recitation of the “suitable donor, a cell culture and a suitable tissue” (Markush group of lines 3-4) anywhere. Applicant is required to point out where these terms, or conceptual equivalents of identical scope, are recited by page and line number.

The amendment of claim 28, has overcome previously stated prior art rejections over Hamerstrom et al. ('086 and '967), Mellonig et al., and Gestrellius

Art Unit: 1644

et al. The amendment has also overcome the provisional obviousness type double patenting rejection over application 09/258,613.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders., Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday - Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Application/Control Number: 09/521,907

Page 5

Art Unit: 1644

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Saunders:jmr

September 17, 2003

David A. Saunders

DAVID SAUNDERS
PRIMARY EXAMINER

ART UNIT ~~182~~ 1644
